(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(b) *Basis for termination of collection action.* Bases on which CMS may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* CMS may terminate collection action if it determines that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, CMS will consider factors such as—

(i) Judicial remedies available;

(ii) The debtor's future financial prospects; and

(iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, CMS may terminate collection action if—

(i) There is no security remaining to be liquidated;

(ii) The applicable statute of limitations has run; or

(iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by CMS to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* CMS may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* CMS may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* CMS may terminate collection action if—

(i) Efforts to obtain voluntary payment are unsuccessful; and

(ii) Evidence or witnesses necessary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* CMS will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, CMS will not allocate the burden of claims payment among the debtors. CMS will proceed with collection action against one debtor even if other liable debtors have not paid their proportionate shares.

(b) *Compromise.* Compromise with one debtor does not release a claim against remaining debtors. Furthermore, CMS will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of CMS claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of CMS appeal procedures.

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

Sec.

Subpart B—Civil Money Penalties and Assessments

Subpart C—Exclusions [Reserved]

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 63 FR 68690, Dec. 14, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 402.1 Basis and scope.

(a) *Basis.* This part is based on the sections of the Act that are specified in paragraph (c) of this section.

(b) *Scope.* This part—

(1) Provides for the imposition of civil money penalties, assessments, and exclusions against persons that violate the provisions of the Act specified in paragraph (c), (d), or (e) of this section; and

(2) Sets forth the appeal rights of persons subject to penalties, assessments, or exclusion and the procedures for reinstatement following exclusion.

(c) *Civil money penalties.* CMS or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(33) of this section under the identified section of the Act. (The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.)

(1) Sections 1833(h)(5)(D) and 1842(j)(2)—Any person that knowingly and willfully, and on a repeated basis, bills for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also include an assessment and cause exclusion.)

(2) Section 1833(i)(6)—Any person that knowingly and willfully presents, or causes to be presented, a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.

(3) Section 1833(q)(2)(B)—Any entity that knowingly and willfully fails to provide information about a referring physician, including the physician's name and unique physician identification number for the referring physician, when seeking payment on an unassigned basis. (This violation, if it occurs in repeated cases, may also cause an exclusion.)

(4) Sections 1834(a)(11)(A) and 1842(j)(2)—Any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A). (This violation may also include an assessment and cause exclusion.)

(5) Sections 1834(a)(18)(B) and 1842(j)(2)—Any nonparticipating durable medical equipment supplier that knowingly and willfully, in violation of section 1834(a)(18)(A), fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also include an assessment and cause exclusion.)

(6) Sections 1834(b)(5)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services. (This violation may also include an assessment and cause exclusion.)

(7) Sections 1834(c)(4)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(4)(B), for mammography screening. (This violation may also include an assessment and cause exclusion.)

(8) Sections 1834(h)(3) and 1842(j)(2)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also include an assessment and cause exclusion.)

(9) Section 1834(j)(2)(A)(iii)—Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully distributes a certificate of medical necessity in violation of section 1834(j)(2)(A)(i) or fails to provide the information required under section 1834(j)(2)(A)(ii).

(10) Sections 1834(j)(4) and 1842(j)(2)—

(i) Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15); or

(C) The service is determined not to be medically necessary or reasonable.

(ii) These violations may also include an assessment and cause exclusion.

(11) Sections 1842(b)(18)(B) and 1842(j)(2)—Any practitioner specified in section 1842(b)(18)(C) (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists) or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(12) Sections 1842(k) and 1842(j)(2)—Any physician who knowingly and willfully presents, or causes to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15). (This violation may also include an assessment and cause exclusion.)

(13) Sections 1842(l)(3) and 1842(j)(2)—Any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A). (This violation may also include an assessment and cause exclusion.)

(14) Sections 1842(m)(3) and 1842(j)(2)—(i) Any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, who knowingly and willfully fails to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program.

(ii) This violation may also include an assessment and cause exclusion.

(15) Sections 1842(n)(3) and 1842(j)(2)—Any physician who knowingly and willfully, in repeated cases, bills one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B). (This violation may also include an assessment and cause exclusion.)

(16) Section 1842(p)(3)(A)—Any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill not submitted on an assignment-related basis for any service furnished by the physician. (This violation, if it occurs in repeated cases, may also cause exclusion.)

(17) Sections 1848(g)(1)(B) and 1842(j)(2)—

(i) Any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis, that—

(A) Knowingly and willfully bills or collects in excess of the limiting charge (as defined in section 1848(g)(2)) on a repeated basis; or

(B) Fails to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv).

(ii) These violations may also include an assessment and cause exclusion.

(18) Section 1848(g)(3)(B) and 1842(j)(2)—Any person that knowingly and willfully bills for State plan approved physicians' services, as defined in section 1848(j)(3), on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may also include an assessment and cause exclusion.)

(19) Section 1848(g)(4)(B)(ii), 1842(p)(3), and 1842(j)(2)(A)—

(i) Any physician, supplier, or other person (except any person that has been excluded from the Medicare program) that, for services furnished after September 1, 1990, knowingly and willfully—

(A) Fails to submit a claim on a standard claim form for services provided for which payment is made under Part B on a reasonable charge or fee schedule basis; or

(B) Imposes a charge for completing and submitting the standard claims form.

(ii) These violations, if they occur in repeated cases, may also cause exclusion.

(20) Section 1862(b)(5)(C)—Any employer (other than a Federal or other governmental agency) that, before October 1, 1998, willfully or repeatedly fails to provide timely and accurate information requested relating to an employee's group health insurance coverage.

(21) Section 1862(b)(6)(B)—Any entity that knowingly, willfully, and repeatedly—

(i) Fails to complete a claim form relating to the availability of other health benefit plans in accordance with section 1862(b)(6)(A); or

(ii) Provides inaccurate information relating to the availability of other health benefit plans on the claim form.

(22) Section 1877(g)(5)—Any person that fails to report information required by HHS under section 1877(f) concerning ownership, investment, and compensation arrangements. (This violation may also include an assessment and cause exclusion.)

(23) Sections 1879(h), 1834(a)(18), and 1842(j)(2)—

(i) Any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15) of the Act; or

(C) The service is determined not to be payable under section 1834(a)(17)(b) because of unsolicited telephone contacts.

(ii) These violations may also include an assessment and cause exclusion.

(24) Section 1882(a)(2)—Any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C). (This violation may also include an assessment and cause exclusion.)

(25) Section 1882(p)(8)—Any person that sells or issues Medicare supplemental policies, on or after July 30, 1992, that fail to conform to the NAIC or Federal standards established under section 1882(p). (This violation may also include an assessment and cause exclusion.)

(26) Section 1882(p)(9)(C)—

(i) Any person that sells a Medicare supplemental policy and—

(A) Fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits; or

(B) Fails to provide the individual, before the sale of the policy, an outline of coverage describing the benefits provided by the policy.

(ii) These violations may also include an assessment and cause exclusion.

(27) Section 1882(q)(5)(C)—

(i) Any person that fails to—

(A) Suspend a Medicare supplemental policy at the policyholder's request, if the policyholder applies for and is determined eligible for medical assistance, and the policyholder provides notice within 90 days of the eligibility determination; or

(B) Automatically reinstate the policy as of the date of termination of medical assistance if the policyholder loses eligibility for medical assistance and the policyholder provides notice within 90 days of loss of eligibility.

(ii) These violations may also include an assessment and cause exclusion.

(28) Section 1882(r)(6)(A)—Any person that fails to provide refunds or credits as required by section 1882(r)(1)(B). (This violation may also include an assessment and cause exclusion.)

(29) Section 1882(s)(4)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Does not waive any time periods applicable to preexisting conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare supplemental policy; or

(B) Denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A).

(ii) These violations may also include an assessment and cause exclusion.

(30) Section 1882(t)(2)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Fails substantially to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(B) Imposes premiums on enrollees in excess of the premiums approved by the State;

(C) Acts to expel an enrollee for reasons other than nonpayment of premiums; or

(D) Does not provide each enrollee at the time of enrollment with the specific information provided in section 1882(t)(1)(E)(i) or fails to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)).

(ii) These violations may also include an assessment and cause exclusion.

(31) Sections 1834(k)(6) and 1842(j)(2)—Any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(32) Sections 1834(l)(6) and 1842(j)(2)—Any supplier of ambulance services who knowingly and willfully bills or collects for any services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(33) Section 1806(b)(2)(B)—Any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.

(d) *Assessments.* CMS or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

(1) Section 1833: Paragraph (h)(5)(D).

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(3) Section 1842: Paragraphs (k), (l)(3), (m)(3), and (n)(3).

(4) Section 1848: Paragraph (g)(1)(B).

(5) Section 1877: Paragraph (g)(5).

(6) Section 1879: Paragraph (h).

(7) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(e) *Exclusions.* (1) CMS or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

(i) Section 1833: Paragraphs (h)(5)(D) and, in repeated cases, (q)(2)(B).

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(iii) Section 1842: Paragraphs (b)(18)(B), (k), (l)(3), (m)(3), (n)(3), and, in repeated cases, (p)(3)(B).

(iv) Section 1848: Paragraphs (g)(1)(B), (g)(3)(B), and, in repeated cases, (g)(4)(B)(ii).

(v) Section 1877: Paragraph (g)(5).

(vi) Section 1879: Paragraph (h).

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), and (t)(2).

(2) CMS or OIG must exclude from participation in the Medicare program any of the following, under the identified section of the Act:

(i) Section 1834(a)(17)(C)—Any supplier of durable medical equipment and supplies that are covered under section 1834(a)(13) that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of covered services in violation of section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts as described under section 1834(a)(17)(A).

(ii) Section 1834(h)(3)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly contacts

Medicare beneficiaries by telephone regarding the furnishing of prosthetic devices, orthotics, or prosthetics in the same manner as in the violation under section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts in the same manner as described in section 1834(a)(17)(C).

(f) *Responsible persons.* (1) If CMS or OIG determines that more than one person is responsible for any of the violations described in paragraph (c) or paragraph (d) of this section, it may impose a civil money penalty or a civil money penalty and assessment against any one of those persons or jointly and severally against two or more of those persons. However, the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person were responsible.

(2) A principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(g) *Time limits.* Neither CMS nor OIG initiates an action to impose a civil money penalty, assessment, or proceeding to exclude a person from participation in the Medicare program unless it begins the action within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.3 Definitions.

For purposes of this part:

Assessment means the amount described in § 402.107 and includes the plural of that term.

Assignment-related basis means that the claim submitted by a physician, supplier or other person is paid on the basis of an assignment, whereby the physician, supplier or other person agrees to accept the Medicare payment as payment in full for the services furnished to the beneficiary and is precluded from charging the beneficiary more than the deductible and coinsurance based upon the approved Medicare fee amount. Additional obligations, including obligations to make refunds in certain circumstances, are established at section 1842(b)(3) of the Act.

Claim means an application for payment for a service for which the Medicare or Medicaid program may pay.

Covered means that a service is described as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service is not covered if it is specifically identified as excluded from Medicare Part B coverage or is not a defined Medicare Part B benefit.

Exclusion means the temporary or permanent barring of a person or other entity from participation in the Medicare or State health care program and that services furnished or ordered by that person are not paid for under either program.

General Counsel means the General Counsel of HHS or his or her designees.

Knowingly or *knowingly and willfully* means that a person, with respect to information—

(1) Has actual knowledge of the information;

(2) Acts in deliberate ignorance of the truth or falsity of the information; or

(3) Acts in reckless disregard of the truth or falsity of the information; and

(4) No proof of specific intent is required.

Medicare supplemental policy means a policy guaranteeing that a health plan will pay a policyholder's coinsurance and deductible and will cover other limitations on payment imposed under title XVIII of the Act and will provide additional health plan or non-Medicare coverage for services up to a predefined benefit limit.

NAIC stands for the National Association of Insurance Commissioners.

Nonparticipating describes a physician, supplier, or other person (excluding any provider of services) that, at the time of furnishing the services to Medicare Part B beneficiaries, is not a participating physician or supplier.

Participating describes a physician or supplier (excluding any provider of services) that, before the beginning of any given year, enters into an agreement with HHS that provides that the physician or supplier will accept payment under the Medicare program on an assignment-related basis for all services furnished to Medicare Part B beneficiaries.

Penalty means the amount described in § 402.105 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physicians' services means the following Medicare covered professional services:

(1) Surgery, consultation, home, office and institutional calls, and other professional services performed by physicians.

(2) Services and supplies furnished ''incident to'' a physician's professional services.

(3) Outpatient physical and occupational therapy services.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens prepared by a physician.

Radiologist service means radiology services performed only by, or under the direction of, a physician who is certified, or eligible to be certified, by the American Board of Radiology or for whom radiology services account for at least 50 percent of the total amount of charges made under part B of title XVIII of the Act.

Request for payment means an application submitted by a person to any person for payment for a service.

Respondent means the person upon which CMS or OIG has imposed, or proposes to impose, a civil money penalty, assessment, or exclusion.

Service includes—

(1) Any item, device, medical supply, or service claimed to have been furnished to a patient and listed in an itemized claim for program payment; or

(2) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Timely basis means that the adjustment to a bill or a refund is considered ''on a timely basis'' if the physician, supplier, or other person makes the adjustment or refund to the appropriate party no later than 30 days after the date the physician, supplier, or other person is notified by the Medicare Part B contractor of the violation and the requirement to refund any excess collections.

§ 402.5 Right to a hearing before the final determination.

CMS or OIG does not make a determination adverse to any person under this part until the person has been given a written notice and opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

§ 402.7 Notice of proposed determination.

(a) If CMS or OIG proposes a penalty and, as applicable, an assessment, or proposes to exclude a respondent from participation in Medicare in accordance with this part, it sends the respondent written notice of its intent by certified mail, return receipt requested. The notice includes the following information:

(1) Reference to the statutory basis or bases for the penalty, assessment, exclusion, or any combination, as applicable.

(2)(i) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment, and exclusion are proposed; or

(ii) If CMS or OIG is relying upon statistical sampling to project the number and types of claims or requests for payment and the dollar amount, a description of the claims and requests for payment comprising the sample and a brief description of the statistical sampling technique CMS or OIG used.

(3) The reason why the claims, requests for payment, or incidents are subject to a penalty and assessment.

(4) The amount of the proposed penalty and of any proposed assessment.

(5) Any mitigating or aggravating circumstances that CMS or OIG considered when it determined the amount of

the proposed penalty and any applicable assessment.

(6) Information concerning response to the notice, including—

(i) A specific statement of the respondent's right to a hearing; and

(ii) A statement that failure to request a hearing within 60 days renders the proposed determination final and permits the imposition of the proposed penalty and any assessment.

(iii) A statement that the debt may be collected through an administrative offset.

(7) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

§ 402.9 Failure to request a hearing.

(a) If the respondent does not request a hearing within 60 days of receipt of the notice of proposed determination specified in § 402.7, any civil money penalty, assessment, or exclusion becomes final and CMS or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) CMS or OIG notifies the respondent by certified mail, return receipt requested, of any penalty, assessment, or exclusion that has been imposed and of the means by which the respondent may satisfy the judgment.

(c) The respondent has no right to appeal a penalty, assessment, or exclusion for which he or she has not requested a hearing.

§ 402.11 Notice to other agencies and other entities.

(a) Whenever a penalty, assessment, or exclusion becomes final, CMS or OIG notifies the following organizations and entities about the action and the reasons for it:

(1) The appropriate State or local medical or professional association.

(2) The appropriate quality improvement organization.

(3) As appropriate, the State agency responsible for the administration of each State health care program (Medicaid, the Maternal and Child Health Services Block Grant Program, and the Social Services Block Grant Program).

(4) The appropriate Medicare carrier or fiscal intermediary.

(5) The appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies).

(6) The long-term care ombudsman.

(b) For exclusions, CMS or OIG also notifies the public and specifies the effective date.

§ 402.13 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

§ 402.15 Collateral estoppel.

(a) When a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 402.1 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

(b) A person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements is barred from denying the essential elements of the criminal offense if the proceedings under this part involve the same transactions.

§ 402.17 Settlement.

CMS or OIG has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time before a final decision by the Secretary. Thereafter, the General Counsel has the exclusive authority.

§ 402.19 Hearings and appeals.

The hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination under this part. For an appeal of a civil money penalty, assessment, or exclusion imposed under this part, either CMS or OIG may represent the government in the hearing and appeals process.

§ 402.21 Judicial review.

After exhausting all available administrative remedies, a respondent may seek judicial review of a penalty, assessment, or exclusion that has become final. The respondent may seek review only with respect to a penalty, assessment, or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this title unless the court excuses the failure or neglect to urge the exception in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

Subpart B—Civil Money Penalties and Assessments

§ 402.105 Amount of penalty.

(a) *$2,000.* Except as provided in paragraphs (b) through (g) of this section, CMS or OIG may impose a penalty of not more than $2,000 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

(b) *$1,000.* CMS or OIG may impose a penalty of not more than $1,000 for the following:

(1) Per certificate of medical necessity knowingly and willfully distributed to physicians on or after December 31, 1994 that—

(i) Contains information concerning the medical condition of the patient; or

(ii) Fails to include cost information.

(2) Per individual about whom information is requested, for willful or repeated failure of an employer to respond to an intermediary or carrier about coverage of an employee or spouse under the employer's group health plan (§ 402.1(c)(20)).

(c) *$5,000.* CMS or OIG may impose a penalty of not more than $5,000 for each violation resulting from the following:

(1) The failure of a Medicare supplemental policy issuer, on a replacement policy, to waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods that were satisfied under a preceding policy (§ 402.1(c)(29)); and

(2) Any issuer of any Medicare supplemental policy denying a policy, conditioning the issuance or effectiveness of the policy, or discriminating in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A). (§ 402.1(c)(29)).

(d) *$10,000.* (1) CMS or OIG may impose a penalty of not more than $10,000 for each day that reporting entity ownership arrangements is late (§ 402.1(c)(22)).

(2) CMS or OIG may impose a penalty of not more than $10,000 for the following violations that occur on or after January 1, 1997:

(i) Knowingly and willfully, and on a repeated basis, billing for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(ii) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(iii) By any durable medical equipment supplier, knowingly and willfully, in violation of section 1834(a)(18)(A), failing to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(iv) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(v) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(vi) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental

basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(vii) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assigned-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(viii) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(xix) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(x) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(xi) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, knowingly and willfully failing to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(xii) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(xiii) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(A) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(B) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv) (§ 402.1(c)(17)).

(xiv) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(xv) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

(3) CMS or OIG may impose a penalty of not more than $10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient therapy or comprehensive rehabilitation services other than on an assignment-related basis.

(4) CMS or OIG may impose a penalty of not more than $10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient ambulance services other than on an assignment-related basis.

(e) *$15,000.* CMS or OIG may impose a penalty of not more than $15,000 if the seller of a Medicare supplemental policy is not the issuer, for each violation described in paragraphs (f)(2) and (f)(3) of this section (§ 402.1 (c)(25) and (c)(26)).

(f) *$25,000.* CMS or OIG may impose a penalty of not more than $25,000 for each of the following violations:

(1) Issuance of a Medicare supplemental policy that has not been approved by an approved State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C) of the Act (§ 402.1(c)(23)).

(2) Sale or issuance after July 30, 1992, of a Medicare supplemental policy that fails to conform with the NAIC or Federal standards established under section 1882(p) of the Act (§ 402.1(c)(25)).

(3) Failure to make the core group of basic benefits available for sale when selling other Medicare supplemental plans with additional benefits (§ 402.1(c)(26)).

(4) Failure to provide, before sale of a Medicare supplemental policy, an outline of coverage describing the benefits provided by the policy (§ 402.1(c)(26)).

(5) Failure of an issuer of a policy to suspend or reinstate a policy, based on the policy holder's request, during entitlement to or upon loss of eligibility for medical assistance (§ 402.1(c)(27)).

(6) Failure to provide refunds or credits for Medicare supplemental policies as required by section 1882(r)(1)(B) (§ 402.1(c)(28)).

(7) By an issuer of a Medicare supplemental policy—

(i) Substantial failure to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(ii) Imposition of premiums on enrollees in excess of the premiums approved by the State;

(iii) Action to expel an enrollee for reasons other than nonpayment of premiums; or

(iv) Failure to provide each enrollee, at the time of enrollment, with the specific information provided in section 1882(t)(1)(E)(i) or failure to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)) (section 1882(t)(2)).

(g) *$100.* CMS or OIG may impose a penalty of not more than $100 for each violation if the person or entity does not furnish an itemized statement to a Medicare beneficiary within 30 days of the beneficiary's request.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

(a) The assessment may not be more than twice the amount claimed for each service that was a basis for the civil money penalty, except for the violations specified in paragraph (b) of this section that occur before January 1, 1997.

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

(1) Knowingly and willfully billing, and on a repeated basis, for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(2) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(3) By any durable medical equipment supplier, knowingly and willfully failing, in violation of section 1834(a)(18)(A), to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(4) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(5) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(6) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental

basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(7) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(i) The supplier does not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for a person or entity specified in sections 1834(k)(6), 1834(l)(6), or 1842(b)(18)(B) (§ 402.1(c)(11), (c)(31), or (c)(32)).

(9) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(10) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(11) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, knowingly and willfully failing to—

(i) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(ii) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(12) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(13) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(i) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(ii) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A) (iii) or (iv) (§ 402.1(c)(17)).

(14) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(15) By any supplier of durable medical equipment, including suppliers of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(i) The supplier did not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.109 Statistical sampling.

(a) *Purpose.* CMS or OIG may introduce the results of a statistical sampling study to show the number and amount of claims subject to sanction under this part that the respondent presented or caused to be presented.

(b) *Prima facie evidence.* The results of the statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitute prima facie evidence of the number and amount of claims or requests for payment subject to sanction under § 402.1.

(c) *Burden of proof.* Once CMS or OIG has made a prima facie case, the burden is on the respondent to produce evidence reasonably calculated to rebut the findings of the statistical

sampling study. CMS or OIG then has the opportunity to rebut this evidence.

§ 402.111 Factors considered in determinations regarding the amount of penalties and assessments.

(a) *Basic factors.* In determining the amount of any penalty or assessment, CMS or OIG takes into account the following:

(1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.

(2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.

(3) The resources available to the person submitting the claim or request for payment or giving the information.

(4) Such other matters as justice may require.

(b) *Criteria to be considered.* As guidelines for taking into account the factors listed in paragraph (a) of this section, CMS or OIG considers the following circumstances:

(1) *Aggravating circumstances of the incident.* An aggravating circumstance is any of the following:

(i) The services or incidents were of several types, occurring over a lengthy period of time.

(ii) There were many of these services or incidents or the nature and circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.

(iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) *Mitigating circumstances.* The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than $1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) *Effect of aggravating or mitigating circumstances.* In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section limits the authority of CMS or OIG to settle any issue or case as provided by §402.19 or to compromise any penalty and assessment as provided by §402.115.

§402.113 When a penalty and assessment are collectible.

A civil money penalty and assessment become collectible after the earliest of the following:

(a) Sixty days after the respondent receives CMS's or OIG's notice of proposed determination under §402.7, if the respondent has not requested a hearing before an ALJ.

(b) Immediately after the respondent abandons or waives his or her appeal right at any administrative level.

(c) Thirty days after the respondent receives the ALJ's decision imposing a civil money penalty or assessment under §1005.20(d) of this title, if the respondent has not requested a review before the DAB.

(d) If the DAB grants an extension of the period for requesting the DAB's review, the day after the extension expires if the respondent has not requested the review.

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under §1005.22(b) of this title.

(f) If the ALJ grants a stay under §1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under §1005.22(b) of this title.

§402.115 Collection of penalty or assessment.

(a) Once a determination by HHS has become final, CMS is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment imposed under this part, after consultation with CMS or OIG, and the Federal government may recover the penalty or assessment in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

Subpart C—Exclusions [Reserved]

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A [Reserved]

Subpart B—Medicare Supplemental Policies

Sec.